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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,295	07/06/2001	Evi Kostenis	02481.1745	7672

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EXAMINER

ULM, JOHN D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 08/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/899,295

**Applicant(s)**

KOSTENIS, EVI

**Examiner**

John D. Ulm

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-9,11-17,19-23,25-37,39-45,47-51 and 53-170 is/are pending in the application.
- 4a) Of the above claim(s) 57-170 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 5-9 11-17 19-23 25-37 39-45 47-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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1) Claims 1 to 3, 5 to 9, 11 to 17, 19 to 23, 25 to 31, 33 to 37, 39 to 45, 47 to 51 and 53 to 170 are pending in the instant application. Claims 4, 10, 18, 24, 32, 38, 46 and 52 have been canceled as requested by Applicant in the correspondence filed of 07 June 2004.

2) Any objection or rejection of record that is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claims 1, 2, 13, 14, 29, 30, 41 and 42 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Conklin et al. publication (Mol. Pharm. 50:885-890, 1996, cited by Applicant) for those reasons of record in section 5 of the previous office action. As stated therein, the assays described in Figures 3 and 4 of this reference met all of the limitations of the instant claims either explicitly or implicitly. For example, it is old and well known in the art that all vertebrate cells produce multiple endogenous G proteins. Therefore, the CHO cells of Conklin et al. inherently meet the "produces at least two G-proteins" limitation of the instant claims.

Applicant has traversed this rejection on the premise that "the preamble and step d)" of claim 1, which recite the limitations "a process for identifying a chemical compound modifying the action of at least one G-protein-coupled receptor (GPCR)-dependent signal transduction pathway of an organism" and "d) determining the quantitative or qualitative effect of the chemical compound or

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compounds of b) on the signal transduction pathway of the cell of a.) by means of a signal transduction pathway-dependent measurable signal” distinguish the claimed method from that which was described in Figures 2, 3 and 4 of the Conklin et al. publication.

Applicant is advised that the preamble of claim 1 is nothing more than a statement of intended use and, therefore does not distinguish the claimed process from the process of the Conklin et al. publication. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997), see M.P.E.P. 2111.02.

Further, any process that measures signal transduction by a G protein-coupled receptor in response to its exposure to a compound is measuring the effect of that compound on “the signal transduction pathway of the cell” “by means of a signal transduction pathway-dependent measurable signal”. Each of the processes described in Figures 2, 3 and 4 of the Conklin et al. publication described the measurement of the effects of a test compound on a signal transduction pathway. Applicant is advised that the very first step in a signal transduction pathway is the activation of a receptor by an agonist. Therefore,

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any process that measures the ligand-activation of a receptor by an agonistic compound is measuring the ability of that chemical compound to modify the action of at least one G-protein-coupled receptor (GPCR)-dependent signal transduction pathway.

Additionally, the processes described in Figures 2, 3 and 4 of the Conklin et al. publication simply exposed a cell to a compound and measured a change in an enzymatic activity of that cell relative to the activity of an otherwise identical cell that had not been exposed to that compound. Therefore, the Conklin et al. publication was measuring the effects of that compound on every element of the signal transduction pathway required to produce the observed changes in the levels of enzymatic activity measured.

Finally, Applicant's arguments are in direct conflict with the instant specification. The only working examples presented in the instant application, Example 3, employ known receptor agonists as the test compounds. This is consistent with the text in paragraph 028 of the instant application, which expressly identifies receptor agonists as compounds that act on a G protein-coupled receptor dependant signal transduction pathway.

5) Claims 1, 2, 13 to 16, 27 to 30, 41 to 44, 55 and 56 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Coward et al. publication (Anal. Biochem. 270:242-248, 01 Jun. 1999, cited by Applicant) for those reasons of record in section 6 of the previous office action.

6) Claims 1 to 56 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Conklin et al. patent publication (WO 99/05177, 04 Feb.

1999, cited by Applicant) in view of the Conklin et al. publication (Mol. Pharm. 50:885-890, 1996, cited by Applicant) for those reasons of record in section 7 of the previous office action.

7) Applicant's arguments filed 07 June of 2004 have been fully considered but they are not persuasive for those reasons given above.

8) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9) This application contains claims 57 to 170, which are drawn to an invention nonelected with traverse in the correspondence of 31 October of 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kunz Gary can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN DLM  
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